The Food and Drug Administration's Center for Devices and Radiological Health has evaluated the material in the Federal Communications Commission's Notice Of Proposed Rule Making: Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields, ET Docket No. 03-137

We support the FCC'S efforts and find the changes in the NRPM commendable. We offer the following comments:

1. Spatial averaging of MPE – It is important that the partial body limit is not exceeded. The FCC should provide more information on how to ensure compliance.

2. Regarding the 100mW SAR exclusion, the basis for 100mW value should be specified.

Devices that operate above 100mW and are designed for use within 20 centimeters of the body should undergo compliance testing to insure they do not exceed the 1.6W/Kg SAR limit.

3. The exclusion Pinna from the 1.6 W/kg local SAR limit

It was stated that the FCC is currently not proposing any rule changes but will consider the issue once IEEE makes their recommendations revising the SAR limit to the pinna (treating the pinna as an extremity). The increase in allowable power deposition will not be significant enough to cause concern.

4. Medical implants emitting RF energy

FDA believes that no adverse health effect will result from this proposed rule change regarding medical implants that emit RF.

However, it is not sufficient to specify only that manufacturers of these implants report the results of computational modeling of patient exposure using finite difference time domain (FDTD) techniques. The FDTD technique may lead to major uncertainty and/or errors if inappropriate parameters and models are used. Interpretation of the results is also not trivial. If FDTD is an option to show compliance, more guidelines and specifications must be supplied in order to avoid ambiguous results. FDTD modeling is not always straightforward. Without guidance, bench testing concepts and comparison to measurements the model and the results can easily be wrong.

FDA is not sure that computational modeling alone can be used to show compliance. One main question is how to scale the results. The real output power or the feed point current must be specified for the transmitting device close to human tissue. Computational modeling must specifically address the behavior of the transmitter very close to tissue. The FCC should identify scientific publications showing that compliance can be shown using numerical modeling. FDA experts in FDTD looked at the computations submitted to the FCC by medical device manufacturers and found some technical irregularities:

a. In one submission it was not specified if the implant lead insulated or if has it contact with the tissue over the whole lead length? FDA has found that lead

insulation affects the maximum SAR significantly.

b. The SAR values were not scaled to the actual transmitted power of -10.5 dB. Instead the calculated input power was used. The SAR values scaled to the real output power of the implant are 3 times higher than the results presented.

d. For one device under study – an implanted cardiac defibrillator (ICD) - the RF output power was 1.5 micro watts. For a cardiac pacemaker the RF power was defined 100 times larger. The SAR values have to be scaled to the maximum possible RF power from the implant.

e. The distance between the antenna and the nearest tissue is critical in defining maximum SAR. Rules for determining this must be standardized.